BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

In the Matter of the Accusation Against:

RHEEM SPECIALTY PHARMACY, LLC dba
RHEEM SPECIALTY PHARMACY, LLC;

JEFFREY M. MORGRIDGE and SAMIRA KHATAMI,

MEMBERS,

Original Pharmacy Permit No. PHY 51285;

and

SAMIRA KHATAMI,
Registered Pharmacist License No. RPH 60045,

Respondents.

Agency Case No. 7120

OAH No. 2022010622

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on November 2, 2022.

It is so ORDERED on October 3, 2022.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

Ву

Seung W. Oh, Pharm.D. Board President

1 2 3 4 5 6 7	ROB BONTA Attorney General of California CHAR SACHSON Supervising Deputy Attorney General GREGORY TUSS Deputy Attorney General State Bar No. 200659 455 Golden Gate Avenue, Suite 11000 San Francisco, CA 94102-7004 Telephone: (415) 510-3435 Facsimile: (415) 703-5480 Attorneys for Complainant	
8 9 10 11	BEFORE BOARD OF P DEPARTMENT OF CO STATE OF CA	PHARMACY ONSUMER AFFAIRS
12 13 14 15 16 17 18 19 20	In the Matter of the Accusation Against: RHEEM SPECIALTY PHARMACY, LLC dba Rheem Specialty Pharmacy, LLC Jeffrey M. Morgridge and Samira Khatami, Members 346 Rheem Blvd, Ste. 109 Moraga, CA 94556 Original Pharmacy Permit No. PHY 51285, SAMIRA KHATAMI 5 Oak Knoll Ln Orinda, CA 94563 Registered Pharmacist License No.	Case No. 7120 OAH No. 2022010622 STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO RESPONDENT SAMIRA KHATAMI
21 22	RPH 60045, Respondents.	
232425	IT IS STIPULATED AND AGREED by a the following matters are true:	and between the parties to these proceedings that
26	<u>PART</u>	TIES
27	1. Anne Sodergren (Complainant) is t	the Executive Officer of the Board of Pharmacy
28	(Board), Department of Consumer Affairs. She bi	rought this action solely in her official capacity
		1

and is represented in this matter by Rob Bonta, Attorney General of the State of California, and Gregory Tuss, deputy attorney general.

- Respondent Samira Khatami (Respondent Khatami) is represented in this proceeding by attorney John D. Bishop, whose address is 4100 Newport Place, Suite 670, Newport Beach, CA 92660.
- 3. On September 13, 2007, the Board issued Original Pharmacist License No. RPH 60045 to Respondent Khatami. This pharmacist license was in full force and effect at all times relevant to the charges brought in Accusation No. 7120 and will expire on October 31, 2022, unless renewed.

JURISDICTION

- 4. Accusation No. 7120 was filed before the Board and is currently pending against Respondent Khatami. The accusation and all other statutorily required documents were properly served on Respondent Khatami on August 2, 2021. Respondent Khatami filed a notice of defense contesting the accusation.
- 5. A copy of Accusation No. 7120 is attached as exhibit 1 and incorporated by reference.

ADVISEMENT AND WAIVERS

- 6. Respondent Khatami has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 7120. Respondent Khatami has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.
- 7. Respondent Khatami is fully aware of her legal rights in this matter, including the right to a hearing on the charges and allegations in the accusation; the right to confront and cross-examine the witnesses against her license; the right to present evidence and to testify on her own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the Administrative Procedure Act and other applicable laws.
 - 8. Respondent Khatami voluntarily, knowingly, and intelligently waives and gives up

each and every right set forth above.

CULPABILITY

- 9. Respondent Khatami understands and agrees that the charges and allegations in Accusation No. 7120, if proven at a hearing, constitute cause for imposing discipline upon her Original Pharmacist License No. RPH 60045.
- 10. For the purpose of resolving the accusation without the expense and uncertainty of further proceedings, Respondent Khatami agrees that, at a hearing, Complainant could establish a factual basis for the charges in the accusation, and that Respondent Khatami gives up her right to contest those charges.
- 11. Respondent Khatami agrees that her pharmacist license is subject to discipline and agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

- 12. This stipulation shall be subject to approval by the Board. Respondent Khatami understands and agrees that counsel for Complainant and the staff of the Board may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent Khatami or her counsel. By signing the stipulation, Respondent Khatami understands and agrees that she may not withdraw her agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.
- 13. The parties understand and agree that portable document format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures, shall have the same force and effect as the originals.
- 14. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings,

discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

15. In consideration of these admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS ORDERED that Original Pharmacist License No. RPH 60045 issued to Respondent Khatami is revoked. However, the revocation is stayed and Respondent Khatami's pharmacist license is placed on probation for three years on the following terms and conditions:

1. Obey All Laws

Respondent Khatami shall obey all state and federal laws and regulations.

Respondent Khatami shall report any of the following occurrences to the Board, in writing, within 72 hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;
- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment;
- a conviction of any crime; or
- discipline, citation, or other administrative action filed by any state or federal agency
 which involves Respondent Khatami's pharmacist license or which is related to the
 practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or
 charging for any dangerous drug, and/or dangerous device or controlled substance.
 Failure to timely report any such occurrence shall be considered a violation of probation.

2. Report to the Board

Respondent Khatami shall report to the Board quarterly, on a schedule as directed by the Board or its designee. The report shall be made either in person or in writing, as directed.

Among other requirements, Respondent Khatami shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the Board.

3. Interview with the Board

Upon receipt of reasonable prior notice, Respondent Khatami shall appear in person for interviews with the Board or its designee at such intervals and locations as are determined by the Board or its designee. Failure to appear for any scheduled interview without prior notification to Board staff, or failure to appear for two or more scheduled interviews with the Board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Respondent Khatami shall timely cooperate with the Board's inspection program and with the Board's monitoring and investigation of Respondent Khatami's compliance with the terms and conditions of the probation, including but not limited to: timely responses to requests for information by Board staff; timely compliance with directives from Board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

5. Continuing Education

Respondent Khatami shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board or its designee.

6. Reporting of Employment and Notice to Employers

During the period of probation, Respondent Khatami shall notify all present and prospective employers of the decision in Accusation No. 7120 and the terms, conditions and restrictions imposed on Respondent Khatami by the decision, as follows:

Within 30 days of the effective date of this decision and within 10 days of undertaking

any new employment, Respondent Khatami shall report to the Board in writing the name, physical address, and mailing address of each of her employer(s), and the name(s) and telephone number(s) of all of her direct supervisor(s), as well as any pharmacist(s)-in- charge, designated representative(s)-in-charge, responsible manager, or other compliance supervisor(s) and the work schedule, if known. Respondent Khatami shall also include the reason(s) for leaving the prior employment. Respondent Khatami shall sign and return to the Board a written consent authorizing the Board or its designee to communicate with all of Respondent Khatami's employer(s) and supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the Board or its designee, concerning Respondent Khatami's work status, performance, and monitoring. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

Within 30 days of the effective date of this decision and within 15 days of Respondent Khatami undertaking any new employment, Respondent Khatami shall cause (a) her direct supervisor; (b) her pharmacist-in-charge, designated representative-in-charge, responsible manager, or other compliance supervisor; and (c) the owner or owner representative of her employer, to report to the Board in writing acknowledging that the listed individual(s) has/have read the decision in Accusation No. 7120 and terms and conditions imposed by the decision and order. If one person serves in more than one role described in (a), (b), or (c), the acknowledgment shall so state. It shall be Respondent Khatami's responsibility to ensure that these acknowledgment(s) are timely submitted to the Board. In the event of a change in the person(s) serving the role(s) described in (a), (b), or (c) during the term of probation, Respondent Khatami shall cause the person(s) taking over the role(s) to report to the Board in writing within 15 days of the change acknowledging that he or she has read the decision in Accusation No. 7120 and the terms and conditions imposed by the decision and order.

If Respondent Khatami works for or is employed by or through an employment service, Respondent Khatami must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the Board of the decision in Accusation No. 7120 and the terms and conditions imposed by the decision and order in advance of Respondent Khatami commencing work at such

licensed entity. A record of this notification must be provided to the Board upon request.

Furthermore, within 30 days of the effective date of this decision and within 15 days of Respondent Khatami undertaking any new employment by or through an employment service, Respondent Khatami shall cause the person(s) described in (a), (b), and (c) above at the employment service to report to the Board in writing acknowledging that he or she has read the decision in Accusation No. 7120 and the terms and conditions imposed by the decision and order. It shall be Respondent Khatami's responsibility to ensure that these acknowledgment(s) are timely submitted to the Board.

Failure to timely notify present or prospective employer(s) or failure to cause the identified person(s) with that/those employer(s) to submit timely written acknowledgments to the Board shall be considered a violation of probation.

"Employment" within the meaning of this provision includes any full-time, part-time, temporary, relief, or employment/management service position as a pharmacist, or any position for which a pharmacist is a requirement or criterion for employment, whether Respondent Khatami is an employee, independent contractor or volunteer.

7. Notification of Change(s) in Name, Address(es), or Phone Number(s)

Respondent Khatami shall further notify the Board in writing within 10 days of any change in name, residence address, mailing address, e-mail address or phone number.

Failure to timely notify the Board of any change in employer, name, address, or phone number shall be considered a violation of probation.

8. Restrictions on Supervision and Oversight of Licensed Facilities

During the period of probation, Respondent Khatami shall not supervise any intern pharmacist, be the pharmacist-in-charge, designated representative-in-charge, responsible manager or other compliance supervisor of any entity licensed by the Board, nor serve as a consultant. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

9. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, Respondent Khatami

shall pay to the Board its costs of investigation and prosecution in the total amount of \$10,000.00. Respondent Khatami is jointly and severally liable with Respondent Rheem Specialty Pharmacy, LLC, for these costs.

Respondent Khatami shall be permitted to pay these costs in a payment plan approved by the Board or its designee, so long as full payment is completed no later than one year prior to the end date of probation. There shall be no deviation from a payment schedule absent prior written approval by the Board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

10. Probation Monitoring Costs

Respondent Khatami shall pay any costs associated with probation monitoring as determined by the Board each and every year of probation. Such costs shall be payable to the Board on a schedule as directed by the Board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

11. Status of License

Respondent Khatami shall, at all times while on probation, maintain an active, current original pharmacist license with the Board, including any period during which suspension or probation is tolled. Failure to maintain an active, current original pharmacist license shall be considered a violation of probation.

If Respondent Khatami's original pharmacist license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions due to tolling or otherwise, upon renewal or reapplication Respondent Khatami's license shall be subject to all terms and conditions of this probation not previously satisfied.

12. License Surrender While on Probation/Suspension

Following the effective date of this decision, should Respondent Khatami cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, Respondent Khatami may relinquish her license, including any indicia of licensure issued by the Board, along with a request to surrender the license. The Board or its designee shall have the discretion whether to accept the surrender or take any other action it deems appropriate

and reasonable. Upon formal acceptance of the surrender of the license, Respondent Khatami will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the Respondent Khatami's license history with the Board.

Upon acceptance of the surrender, Respondent Khatami shall relinquish her pocket and/or wall license, including any indicia of licensure not previously provided to the Board, within 10 days of notification by the Board that the surrender is accepted if not already provided.

Respondent Khatami may not reapply for any license from the Board for three years from the effective date of the surrender. Respondent Khatami shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board, including any outstanding costs.

13. Practice Requirement – Extension of Probation

Except during periods of suspension, Respondent Khatami shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 80 hours per calendar month. Any month during which this minimum is not met shall extend the period of probation by one month. During any such period of insufficient employment, Respondent Khatami must nonetheless comply with all terms and conditions of probation, unless Respondent Khatami receives a waiver in writing from the Board or its designee.

If Respondent Khatami does not practice as a pharmacist in California for the minimum number of hours in any calendar month, for any reason (including vacation), Respondent Khatami shall notify the Board in writing within 10 days of the conclusion of that calendar month. This notification shall include at least: the date(s), location(s), and hours of last practice; the reason(s) for the interruption or reduction in practice; and the anticipated date(s) on which Respondent Khatami will resume practice at the required level. Respondent Khatami shall further notify the Board in writing within 10 days following the next calendar month during which Respondent Khatami practices as a pharmacist in California for the minimum of hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for Respondent Khatami's probation to be extended under the

provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding 36 months. The Board or its designee may post a notice of the extended probation period on its website.

14. Violation of Probation

If Respondent Khatami has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent Khatami, and the Board shall provide notice to Respondent Khatami that probation shall automatically be extended until all terms and conditions have been satisfied or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The Board or its designee may post a notice of the extended probation period on its website.

If Respondent Khatami violates probation in any respect, the Board, after giving Respondent Khatami notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against Respondent Khatami during probation, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the Board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided, and the charges and allegations in the accusation shall be deemed true and correct.

15. Completion of Probation

Upon written notice by the Board or its designee indicating successful completion of probation, Respondent Khatami's pharmacist license will be fully restored.

16. Community Services Program

Within 60 days of the effective date of this decision, Respondent Khatami shall submit to the Board or its designee, for prior approval, a community service program in which Respondent Khatami shall provide free pharmacist services on a regular basis to a community or charitable facility or agency for at least four hours per month for the duration of probation. Within 30 days of Board approval, Respondent Khatami shall submit documentation to the Board or its designee

demonstrating commencement of the community service program. Respondent Khatami shall report on progress with the community service program in the quarterly reports and provide satisfactory documentary evidence of such progress to the Board or its designee upon request. Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

17. Remedial Education

Within 60 days of the effective date of this decision, Respondent Khatami shall submit to the Board or its designee, for prior approval, an appropriate program of remedial education related to corresponding responsibility. The program of remedial education shall consist of at least 12 hours per year of probation, at Respondent Khatami's own expense. Fifty percent of the hours shall be completed live in-person or by live webinar. All remedial education shall be in addition to and shall not be credited toward continuing education (CE) courses used for license renewal purposes for pharmacists.

Failure to timely submit for approval or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the Board, is provided to the Board or its designee.

Following the completion of each course, the Board or its designee may require Respondent Khatami, at her own expense, to take an approved examination to test her knowledge of the course. If Respondent Khatami does not achieve a passing score on the examination that course shall not count towards satisfaction of this term. Respondent Khatami shall take another course approved by the Board in the same subject area.

18. Ethics Course

Within 60 calendar days of the effective date of this decision, Respondent Khatami shall enroll in a course in ethics, at Respondent Khatami's expense, approved in advance by the Board or its designee that complies with California Code of Regulations, title 16, section 1773.5.

Respondent Khatami shall provide proof of enrollment upon request. Within five days of completion, Respondent Khatami shall submit a copy of the certificate of completion to the Board

1	or its designee. Failure to timely enroll in an approved ethics course, to initiate the course during	
2	the first year of probation, to successfully complete it before the end of the second year of	
3	probation, or to timely submit proof of completion to the Board or its designee, shall be	
4	considered a violation of probation.	
5	19. No New Ownership or Management of Licensed Premises	
6	Respondent Khatami shall not acquire any new ownership, legal or beneficial interest nor	
7	serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any	
8	additional business, firm, partnership, or corporation licensed by the Board for two years from the	
9	effective date of this decision. The Board shall retain the discretion whether to grant or deny any	
10	application for new ownership, or take any other action it deems appropriate and reasonable. If	
11	Respondent Khatami currently owns or has any legal or beneficial interest in, or serves as a	
12	manager, administrator, member, officer, director, trustee, associate, or partner of any business,	
13	firm, partnership, or corporation currently or afterward licensed by the Board, Respondent	
14	Khatami may continue to serve in such capacity or hold that interest, but only to the extent of that	
15	position or interest as of the effective date of this decision. Violation of this restriction shall be	
16	considered a violation of probation.	
17	<u>ACCEPTANCE</u>	
18	I have carefully read the above Stipulated Settlement and Disciplinary Order and have	
19	fully discussed it with my attorney, John Bishop. I understand the stipulation and the effect it wi	
20	have on my pharmacist license. I enter into this Stipulated Settlement and Disciplinary Order	
21	voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the	
22	Board.	
23		
24	DATED:	
25	SAMIRA KHATAMI Respondent	
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STIPULATED SETTLEMENT AS TO RESPONDENT KHATAMI (7120)

or its designee. Failure to timely enroll in an approved ethics course, to initiate the course during the first year of probation, to successfully complete it before the end of the second year of probation, or to timely submit proof of completion to the Board or its designee, shall be considered a violation of probation.

19. No New Ownership or Management of Licensed Premises

Respondent Khatami shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the Board for two years from the effective date of this decision. The Board shall retain the discretion whether to grant or deny any application for new ownership, or take any other action it deems appropriate and reasonable. If Respondent Khatami currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or afterward licensed by the Board, Respondent Khatami may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, John Bishop. I understand the stipulation and the effect it will have on my pharmacist license. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board.

DATED:	7/21/2022	Samira Eliatami
		SAMIRA KIPATIATIF 649A Respondent
///		

1	I have read and fully discussed with Respondent Khatami the terms and conditions and
2	other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its
3	form and content.
4	DATED:
5	JOHN BISHOP Attorney for Respondent Khatami
6	<u>ENDORSEMENT</u>
7	This Stipulated Settlement and Disciplinary Order is submitted for consideration by the
8	Board.
9	DATED: D
10	DATED: Respectfully submitted,
11	ROB BONTA Attorney General of California CHAR SACHSON
12	Supervising Deputy Attorney General
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1415	GREGORY TUSS Deputy Attorney General Attorneys for Complainant
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2	other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its
3	form and content.
4	DATED:
5	JOHN BISMOP DOSFC1485 Attorney for Respondent Khatami
6	<u>ENDORSEMENT</u>
7	This Stipulated Settlement and Disciplinary Order is submitted for consideration by the
8	Board.
9	DATED B. (CII. 1. IV. 1
10	DATED: Respectfully submitted,
11	ROB BONTA Attorney General of California CHAR SACHSON
12	Supervising Deputy Attorney General
13	
14	GREGORY TUSS
15	Deputy Attorney General Attorneys for Complainant
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3	form and content.
4	DATED:
5	JOHN BISHOP Attorney for Respondent Khatami
6	<u>ENDORSEMENT</u>
7	This Stipulated Settlement and Disciplinary Order is submitted for consideration by the
8	Board.
9	8-5-22 DATED 8-5-22
10	DATED: Respectfully submitted,
11	ROB BONTA Attorney General of California
12	CHAR SACHSON Supervising Deputy Attorney General
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14	GREGORY TUSS
15	Deputy Attorney General Attorneys for Complainant
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Exhibit 1

Accusation No. 7120

1	ROB BONTA Attorney General of California		
2	Attorney General of California CHAR SACHSON		
3	Supervising Deputy Attorney General JONATHAN D. COOPER		
4	Deputy Attorney General State Bar No. 141461		
5	455 Golden Gate Avenue, Suite 11000 San Francisco, CA 94102-7004 Telephone: (415) 510-3433		
6	Facsimile: (415) 703-5480 Attorneys for Complainant		
7	Thiorneys for Complainain		
8	BEFOR BOARD OF F		
9	DEPARTMENT OF CO	ONSUMER AFFAIRS	
10	STATE OF C.	ALIFORNIA	
11			
12	In the Matter of the Accusation Against:	Case No. 7120	
13	RHEEM SPECIALTY PHARMACY, LLC dba Rheem Specialty Pharmacy, LLC		
14	Jeffrey M. Morgridge and Samira Khatami, Members	ACCUSATION	
15	346 Rheem Blvd, Ste. 109 Moraga, CA 94556		
16	Original Pharmacy Permit No. PHY 51285		
17	And		
18	SAMIRA KHATAMI 5 Oak Knoll Ln		
19	Orinda, CA 94563		
20 21	Registered Pharmacist License No. RPH 60045		
22	Respondents.		
23			
24			
25	PAR	<u> TIES</u>	
26	1. Anne Sodergren (Complainant) bring	s this Accusation solely in her official capacity	
27	as the Executive Officer of the Board of Pharmac	y, Department of Consumer Affairs (Board).	
28	2. On or about July 8, 2013, the Board is	ssued Original Pharmacy Permit Number PHY	
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51285 to Rheem Specialty Pharmacy, LLC, dba Rheem Specialty Pharmacy, LLC, Jeffrey M. Morgridge and Samira Khatami, Members (hereinafter "Respondent Rheem"). The Original Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein. It was cancelled on November 18, 2020.

3. On or about September 13, 2007, the Board issued Original Pharmacist License Number RPH 60045 to Samira Khatami (hereinafter "Respondent Khatami"). The Registered Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on October 31, 2022, unless renewed. Respondent Khatami served as Pharmacist-in-Charge for Respondent Rheem since July 8, 2013.

JURISDICTION

- 4. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.
- 5. Section **4011** of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].
- 6. Section **4300(a)** of the Code provides that every license issued by the Board may be suspended or revoked.
- 7. Section **4300.1** of the Code provides that the expiration, cancellation, forfeiture, or suspension of a Board-issued license, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee, shall not deprive the Board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

STATUTORY AND REGULATORY PROVISIONS

Business and Professions Code:

- 8. Section **4059** of the Code, in pertinent part, prohibits furnishing of any dangerous drug or dangerous device except upon the prescription of an authorized prescriber.
 - 9. Section **4081** of the Code states, in pertinent part:

(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or
dangerous devices shall be at all times during business hours open to inspection by authorized
officers of the law, and shall be preserved for at least three years from the date of making. A
current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-
animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital,
institution, or establishment holding a currently valid and unrevoked certificate, license, permit,
registration, or exemption under Division 2 (commencing with Section 1200) of the Health and
Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and
Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated representative-in-charge, for maintaining the records and inventory described in this section.

. . .

- 10. Section **4105** of the Code requires, in pertinent part, that unless a waiver is granted by the board, all records and other documentation of the acquisition and disposition of dangerous drugs and devices by any entity licensed by the board be retained on the licensed premises, in a readily retrievable form, for three years from the date of making.
 - 11. Section **4113(c)** of the Code states:

The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

12. Section **4301** of the Code states, in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

. .

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

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(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

. . .

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

. . .

13. Section **4306.5** of the Code states:

Unprofessional conduct for a pharmacist may include any of the following:

- (a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.
- (b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.
- (c) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.
- (d) Acts or omissions that involve, in whole or in part, the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.
 - 14. Section 4307 of the Code states:
- (a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or

any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

- (1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.
- (2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.
- (b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.
- (c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

15. Section **4332** of the Code states:

Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor.

California Code of Regulations:

- 16. California Code of Regulations, title 16, section **1715** states:
- (a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

. . .

- (d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed.
 - 17. California Code of Regulations, title 16, section **1718** states:

"Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.

The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

18. California Code of Regulations, title 16, section 1735.2 states, in pertinent part:

. . .

(k) Prior to allowing any drug product preparation to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30

days of the start date of a new pharmacist-in-charge or change of location, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

. . .

- 19. California Code of Regulations, title 16, section 1735.3 states, in pertinent part:
- (a) For each compounded drug preparation, pharmacy records shall include:
- (1) The master formula document.
- (2) A compounding log consisting of a single document containing all of the following:
- (A) Name and Strength of the compounded drug preparation.
- (B) The date the drug preparation was compounded.
- (C) The identity of any pharmacy personnel engaged in compounding the drug preparation.
- (D) The identity of the pharmacist reviewing the final drug preparation.
- (E) The quantity of each ingredient used in compounding the drug preparation.
- (F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply.
- (i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile preparations compounded in a single lot for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference.
- (G) A pharmacy-assigned unique reference or lot number for the compounded drug preparation.
- (H) The beyond use date or beyond use date and time of the final compounded drug preparation, expressed in the compounding document in a standard date and time format.

- (I) The final quantity or amount of drug preparation compounded for dispensing.
- (J) Documentation of quality reviews and required post-compounding process and procedures.

. . .

- 20. California Code of Regulations, title 16, section 1735.5 states, in pertinent part:
- (a) Any pharmacy engaged in compounding shall maintain written policies and procedures for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action.
- (b) The policies and procedures shall be reviewed and such review shall be documented on an annual basis by the pharmacist-in-charge. The policies and procedures shall be updated whenever changes in policies and procedures are implemented.

. . .

- 21. California Code of Regulations, title 16, section 1735.7 states:
- (a) A pharmacy engaged in compounding shall maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating that all personnel involved in compounding are trained in all aspects of policies and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the compounding process.
- (b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.
- (c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug preparation.

- 22. California Code of Regulations, title 16, section 1735.8 states:
- (a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug preparations.
- (b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.
- (c) The quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, including the frequency of testing. All qualitative and quantitative analysis reports for compounded drug preparations shall be retained by the pharmacy and maintained along with the compounding log and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.
- (d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug preparation is ever discovered to be outside minimum standards for integrity, potency, quality, or labeled strength.
- (e) The quality assurance plan shall include a written procedure for responding to out-ofrange temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing.

Controlled Substances/Dangerous Drugs:

- 23 Section **4021** of the Code provides that a "controlled substance" means any substance listed in Schedules I through V contained in Health and Safety Code section 11053 et seq.
 - 24. Section 4022 of the Code states, in pertinent part:

"Dangerous drug: or "dangerous device" means any drug or device unsafe for self use, except veterinary drugs that are labeled as such, and includes the following:

(23.a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import. . . .

- (c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.
 - 25. California Health and Safety Code section 11153 states:
- (a) A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use.
- (b) Any person who knowingly violates this section shall be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or in a county jail not exceeding one year, or by a fine not exceeding twenty thousand dollars (\$20,000), or by both that fine and imprisonment.
- (c) No provision of the amendments to this section enacted during the second year of the 1981-82 Regular Session shall be construed as expanding the scope of practice of a pharmacist.

COST RECOVERY

26. Section **125.3** of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

PHARMACY LAW VIOLATIONS

27. On or about October 29, 2020, a Pharmacy Board Inspector inspected Respondent Rheem. The inspection revealed numerous violations of standards applicable to pharmacies, as follows:

- a. <u>Self-Assessment of Pharmacy</u>: Respondent Rheem and Respondent Khatami (hereinafter "Respondents") failed to comply with California Code of Regulations, title 16, section 1715, subsections (a) and (d), which require pharmacies to complete and keep on file self-assessments of the pharmacies' compliance with federal and state pharmacy law.
- b. <u>Self-Assessment Regarding Compounding Limitations and Requirements</u>:

 Respondents failed to comply with California Code of Regulations, title 16, section 1735.2, subsection (k), which requires compounding pharmacies to complete and keep on file self-assessments of the pharmacies' compliance with federal and state pharmacy law.
- c. <u>Compounding Log</u>: Respondents failed to comply with California Code of Regulations, title 16, section 1735.3, subsection (a)(2)(J), which requires compounding pharmacies to maintain a compounding log documenting quality reviews and required post-compounding process and procedures.
- d. <u>Compounding Policies and Procedures</u>: Respondents failed to comply with California Code of Regulations, title 16, section 1735.5, subsection (b), which requires compounding pharmacies to maintain written policies and procedures for compounding and to update them on an annual basis. On the date of the inspection, the compounding policies and procedures had not been updated or reviewed since 2014.
- e. <u>Compounding Quality Assurance</u>: Respondents failed to comply with California Code of Regulations, title 16, section 1735.8, which requires compounding pharmacies to maintain a written quality assurance plan designed to monitor and ensure the integrity, potency, quality and strength of compounded drug preparations. On the date of the inspection, Respondents failed to show that they had completed end product testing to ensure the potency and labeled strength on any compounded drug product.
- f. Training of Compounding Staff: Respondents failed to comply with California Code of Regulations, title 16, section 1735.7, which requires compounding pharmacies to train, evaluate and assess the ongoing competency of pharmacy staff, and to maintain documentation of compliance with these requirements. On the date of the inspection, Respondents failed to show that they had complied with these requirements.

- g. <u>Fraudulent Conduct</u>: Respondents engaged in unprofessional conduct, in violation of Code section 4301, subsection (f), by engaging in fraudulent acts. Between November 1, 2018 and October 29, 2020, Respondents filled fraudulent prescriptions for foot bath treatments. The prescriptions were purportedly issued by medical practitioners. The practitioners, however, did not in actuality issue or authorize the prescriptions. Respondents billed for prescriptions that were never written and/or were never filled.
- h. <u>Failure to Maintain Current Inventory</u>: Respondents failed to comply with Code section 4081, subsection (a), and California Code of Regulations, title 16, section 1718, which require pharmacies to maintain a current inventory of manufacture, sale, acquisition and disposition of dangerous drugs and devices. A two-year audit from November 1, 2018 to October 29, 2020 revealed substantial overages of vancomycin, clindamycin and ketoconazole. In other words, the audit revealed that Respondents had dispensed more of these drugs than Respondents had purchased.

FIRST CAUSE FOR DISCIPLINE

(Failure to Comply with Pharmacy Laws)

28. Respondents are each and severally subject to discipline under Code sections 4113, subsection (c), 4301, subsections (j) and (o), and, by reference to section(s) 4081, 4105 and/or 4332 of the Code, for violating laws regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, as set forth above in paragraph 27 and its subsections.

SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct -- Fraud)

29. Respondents are each and severally subject to discipline under section 4301(f) of the Code and under Code section 4113, subsection (c), in that Respondents committed acts involving moral turpitude, dishonesty, fraud, deceit, or corruption, as set forth above in paragraph 27 and its subsections.

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THIRD CAUSE FOR DISCIPLINE

Respondents are each and severally subject to discipline under section 4301 of the Code and under Code section 4113, subsection (c), in that Respondents committed acts of unprofessional conduct, as set forth above in paragraph 27 and its subsections.

(Pharmacist's Failure to Exercise Education, Training and Experience)

Respondent Khatami is subject to discipline under section 4306.5 of the Code in that she inappropriately exercised her education, training or experience as a pharmacist, as set forth

- Pursuant to Code section 4307, if discipline is imposed on Pharmacy Original Permit Number PHY 51285 issued to Respondent Rheem, then Respondent Rheem shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 51285 is placed on probation or until Pharmacy Permit Number PHY 51285 is reinstated if it is revoked.
- Pursuant to Code section 4307, if discipline is imposed on Pharmacist License Number RPH 60045, issued to Respondent Khatami, then Respondent Khatami shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 60045 is placed on probation or until Pharmacist License Number RPH 60045 is reinstated if it is revoked.

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,

- Revoking or suspending Original Permit Number PHY 51285 issued to Respondent
- Revoking or suspending Pharmacist License Number RPH 60045, issued to